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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/631,637	08/02/2000	Jean Gosselin	2097/49123	8660

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EXAMINER

WINKLER, ULRIKE

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 01/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/631,637

Applicant(s)

GOSSELIN ET AL.

Examiner

Ulrike Winkler, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 11-15 and 17-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Applicant's election with traverse of group I, with the election of retroviruses as a distinct invention. In addition, the following species have also been elected: human, oral administration and tablets in Paper No. 6 is acknowledged. The traversal is on the grounds that group II, by virtue of its dependency fall within the scope of group I. This is not found persuasive because group I is drawn to a treatment method that requires a single drug application while group II is drawn to a method of treatment that requires a combination of drugs; therefore the search for one group will not be coextensive with the search for the other group and it would be an undue burden on the office. The requirement is still deemed proper and is therefore made FINAL.

Claims 1-10 and 16 are drawn to the elected invention, claims 11-15, 17-56 are withdrawn because they drawn to a non-elected invention.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, Paper No. 4, is attached to the instant Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4, 6-10 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "treatment of an infection" renders the claims

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indefinite because the ordinary artisan would not know the metes and bounds of this term. Does this mean the infection is eliminated or that viral load is reduced or that the symptoms of the viral infection are ameliorated, i.e., a higher CD4+ count. In addition, it is not clear what type of infection is contemplated such as bacterial, viral or parasitic. Therefore, the term is indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 6-10 and 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to a method for treatment of a viral infection, specifically a retroviral infection such as HIV, comprising administering a therapeutically effective amount of a peroxovanadium compound. While the specification provides some data which is obtained from tissue culture cells, the specification provides no exemplification of treating a patient with the compound and obtaining the desired result.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). They include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

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The specification does not provide sufficient guidance for the treatment of a patient with a peroxovanadium compound for treating a viral infection, specifically HIV. The examples provided in the specification (see figures) are in direct conflict with what is known in the prior art. The prior art indicates that treating HIV infected cells with peroxovanadium compounds causes activation of HIV transcription from the LTR (Barbeau et al., Journal of Biological Chemistry, 1997, see abstract and figure 1). The prior art also discloses an increase in the reverse transcriptase activity in the supernatant indicating that the treatment with peroxovanadium compounds results in an increase in particle release (see 8 and 9). The ordinary artisan would not interpret an increase of HIV particle release from cells to be a treatment for an HIV infection. This would be a way of increasing the viral load in a patient which is not a desired treatment. Thus, the lack of working examples regarding treatment of any retroviral infection including HIV in a patient, the lack of guidance in the specification, and the unpredictability regarding treatment of viral infections greatly reduces the probability that one of skill in the art would successfully obtain the claimed invention without undue experimentation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Oliver et al. (Journal of Biological Chemistry, 1998).

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The instant invention is drawn to a method of treating an infection in a patient by administering an effective amount of a peroxovanadium compound.

Oliver et al. teach treating mice with *Leishmania* infection using peroxovanadium compounds (see abstract, figure 1, figure 3 and table 1). Therefore, the instant invention is anticipated by Oliver et al.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Ulrike Winkler, Ph.D.



JEFFREY STUCKER
PRIMARY EXAMINER